

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1-11 and 18-34 are now pending in this application.

Claims 12-17 have been canceled.

Claims 29-34 have been added and claims 1-4, 8, 9, 11, 18-20 and 22-28 have been amended in order to more particularly point out and distinctly claim the invention.

The amendments to claims 1-4 are fully supported within original claims 1-4 and within the examples. The amendments to claims 8 and 9 are formal in nature. The amendments to claim 11 are supported within original claim 2 and originally pending now canceled claims 12 and 13. The amendments to claims 18 and 19 are formal in nature. The amendments to claim 20 are formal and made in response to the Examiner's rejection to the term "true value". The amendments to claim 22 are formal and based on the amendments to claim 20. The amendments to claim 23 are supported within original claim 2 and the examples. The amendments to claims 24-28 are formal in nature. Newly added claims 29-34 are supported within the examples and within original claims 1, 2, 10 and 13.

No new matter has been added.

**Objections to the Specification**

The specification was objected to as not referring to terminology contained within original claims 8, 14 and 19. Applicant points out that the specification could be amended to include the language contained within the original claims. However, in that the claims have been amended to delete the specific terms objected to, amendments to the specification are not believed to be necessary and the objection is believed to have been rendered moot.

**Obviousness-Type Double Patenting Rejection**

Claims 17-19 were rejected under the judicially created doctrine of obviousness-type double patenting. This rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicant points out that claim 17 has been canceled. Further, claims 18 and 19 have been made dependent on the "preparation" claim 1. In view of these claim amendments the rejection is believed to have been rendered moot.

**Rejection under 35 U.S.C. §112, first paragraph**

Numerous rejections have been made against the original claims. Although applicant does not acquiesce to these rejections applicant wishes to expedite prosecution of the application. Accordingly, certain amendments have been made to the claims which render these objections moot.

First, claim 1 has been amended to indicate that the prions are from a plurality of transgenic mice brains. This renders moot the objections made to the claims encompassing subject matter relating to other transgenic animals.

Secondly, claim 1 has been amended to indicate that the prions infect and cause disease in an animal chosen from a human, a cow, and a sheep. The PrP gene for a human, a cow and a sheep are known and the sequences can be readily accessed by those skilled in the art.

The Office Action also points out that the specific examples are limited to examples wherein both of the endogenous PrP genes have been ablated. Although the examples are limited to such applicant was the first to demonstrate how to produce prions in a transgenic mouse brain by the insertion of an exogenous PrP gene. Although a specific example is not provided wherein only one endogenous allele is ablated applicant should be given some breadth in their invention and some leeway with respect to what might be expected to be operable. Now that applicant has shown the world methods of producing transgenic animals and of using the homogenized brains of those animals to produce standardized prion preparations others could use applicant's teachings with alternate means for producing such prions which might involve techniques that may not require ablating both endogenous PrP genes. In view of such, applicant respectfully requests reconsideration with respect to this point even though new claims have been added which are specific to embodiments wherein both endogenous PrP genes have been ablated.

In addition, applicant points out that claim 9 includes a number of specific examples of transgenic mice which would be expected to be operable in connection with applicant's invention. Claim 9 has been amended to eliminate reference to transgenic mice which have a hamster PrP gene therein thereby rendering moot the rejections based on prior art which show the use of mice which have hamster PrP genes inserted therein.

Claims 17-19 were rejected based on substantially the same reasons as original claim 1-10 and 11-16. However, claim 17 has now been canceled and claims 18 and 19 made dependent on claim 1.

For the reasons indicated above claims 18 and 19 are believed to be amended in a form so as to render the objections moot.

### **35 U.S.C. §112, second paragraph Rejections**

The claims have been amended to eliminate the term “characterized by” objected to by the Examiner in order to expedite prosecution even though applicant does not acquiesce to the rejection. The objection to claim 2 has been rendered moot in view of amendments to claim 1 which eliminate the use of the term “amount” thereby eliminating any perceived conflict with the term “concentration”.

Claims 3 and 4 have been amended to eliminate the use of the terms “comprised of” and “substantially all” thereby rendering the objections directed to these terms moot.

The language “groups consisting of” has been deleted from claim 8 thereby rendering this rejection moot.

The objections to claims 8, 14 and 19 have been rendered moot by claim amendments and/or cancellations. The objections to claim 11 have been rendered moot by amending claim 11 to refer to the specific properties and prion measurement protocols. The objection to claim 13 has been overcome by the amendments made to claim 11 and the cancellation of claim 13 from the application. The rejections of claims 14 and 15 have been rendered moot by the cancellation of these claims from the application.

The rejection of claims 20-22 relating to the term “a true value” has been overcome by deleting this term and adding the term –actual value--.

### **Rejections under 35 U.S.C. §102**

Claims 1, 4, 7 and 9 were rejected under 35 U.S.C. §102 as anticipated by Scott et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

In response, applicant points out that claim 1 has been amended to include limitations contained within claims not indicated as being anticipated by Scott et al. For example, the transgenic mouse brains comprise prions which infect and cause disease in an animal chosen from a human, a cow and a sheep whereas Scott et al. is limited to hamsters. Hamsters are not genetically diverse from mice with respect to their PrP gene and as such Scott et al. do not anticipate the claims or render them obvious within the meaning of 35 U.S.C. §103.

Claims 1, 4, and 7 were rejected as anticipated by Caughey et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Claim 1 has been amended to indicate that the prions infect and cause disease in an animal chosen from a human, a cow and a sheep. This was not taught or suggested within Caughey et al. which is limited to mice. In view of such the rejection is believed to have been overcome.

### **Rejection under 35 U.S.C. §103**

Claims 20-28 were rejected under 35 U.S.C. §103 as unpatentable over Scott et al. The rejection is traversed as applied and as it might be applied against the presently pending claims.

Scott et al. is limited to hamster prions. Scott et al. did not contemplate a method whereby it would be possible to create prions which would infect a human, a cow or a sheep. The PrP gene of a hamster is genetically similar to that of a mouse whereas the PrP gene of a mouse is genetically diverse as compared to that of a human, a cow or a sheep making it substantially more difficult to produce prions which would infect these mammals using a transgenic mouse. Applicant needed to produce such prions in order to provide for the method of calibration of the prion assay now claimed in claims 20-28.

The rejection indicates that the methods “require only an appropriate prion preparation.” However, Scott et al. do not disclose such a preparation which would meet the limitations of currently amended claim 20 and such is also true with respect to amended claim 23 thereby overcoming the rejection based on Scott et al.

### **Conclusion**

The objections to the specification are overcome by claim amendments and claim cancellations. The double patenting rejection is overcome by claim amendments and cancellations. The specific 35 U.S.C. §112 rejections although not acquiesced to are believed to have been rendered moot by claim amendments wherein applicant has limited the claims to transgenic mice which mice produce prions which infect and cause disease in a human, a cow or a sheep. Some breadth should be afforded to applicant's invention even though the specific examples are limited to the ablation of both alleles of the endogenous mouse PrP gene. While not acquiescing to the specific claim rejections applicant again wishes to expedite prosecution and have made amendments to the claims in order to overcome the objections raised by the Examiner. The art related rejections are believed to have been overcome in view of claim amendments and by pointing out that Scott et al. is limited to mice which produce hamster prions and Caughey et al. is limited to mouse prions. In view of such all of the rejections are believed to

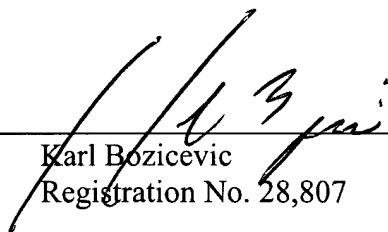
have been rendered moot or overcome and an indication of allowability of the application is respectfully requested.

In the event that minor issues remain unresolved the Examiner is respectfully requested to contact the undersigned attorney at the indicated telephone number to arrange for an interview to disposition of this application.

In the event any fees are due in connection with the filing of this amendment or extensions are required applicant petitions for any required extensions and authorize the Commissioner to charge the cost of such extensions or other required fees to our Deposit Account No. 50-0815, order number UCAL-056CIP4.

Respectfully submitted,  
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Date: 3/Nov/03

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